K101885

APR -1 8 2011

Section 6

510(k) Summary

Submission Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371 ph: (330) 425-1313 fax: (330) 963-0749
Contact:	Douglas J. Thistlethwaite
Date:	July 1, 2010
Establishment Registration No.	1528028
Trade/Proprietary Name:	HITACHI SCENARIA Whole-body X-ray CT System
Classification Name:	Computed Tomography X-ray System
Product Code	JAK
C.F.R. Section:	892.1750
Regulatory Class	Class II
Predicate Device(s):	TOSHIBA AQUILION 64 Slice System (K080211)
Reason for Submission	New Device

Device Intended Use

The SCENARIA system is indicated to acquire axial volumes of the whole body including the head. The images can be acquired in either axial, helical, gated or dynamic modes.

The volume datasets acquired by the SCENARIA can be post processed by the SCENARIA to provide additional information. Post processing capabilities included in the SCENARIA software include CT angiography (CTA), Multi-planar reconstruction (MPR) and volume rendering.

Volume datasets acquired by the SCENARIA can be transferred to external devices via a DICOM standard interface.

Device Description

Function

The SCENARIA is a multi-slice computed tomography system that uses x-ray data to produce cross-sectional images of the body at various angles.

Scientific Concepts

The SCENARIA system uses 64-slice CT technology, where the X-ray tube and detector assemblies are mounted on a frame that rotates continuously around the patient using slip ring technology. The solid-state detector assembly design collects up to 64 slices of data simultaneously. The X-ray sub-system features a high frequency generator, X-ray tube, and collimation system that produces a fan beam X-ray output. The system can operate in a helical (spiral) scan mode where the patient table moves during scanning. As the X-ray tube/detector assembly rotates around the patient, data is collected at multiple angles.

The collected data is then reconstructed into cross-sectional images by a high-speed reconstruction sub-system. The images are displayed on a Computer Workstation, stored, printed, and archived as required. The workstation is based on current PC technology using the Windows™ operating system.

Physical and Performance Characteristics

The SCENARIA system consists of a Gantry, Operator's Workstation, Patient Table, high-Frequency X-ray Generator, and accessories. The system performance is similar to the predicate device.

Performance Comparison

A clinical evaluation comparison was conducted with the SCENARIA system and the TOSHIBA Aquillion 64 Slice System and found to be substantially equivalent as documented in Section 17 – Performance Testing – Clinical.

In addition, evaluations were conducted for dose profile, image noise, Modulation Transfer Function (MTF), slice thickness and sensitivity profile, slice plane location, and CT dose index as documented in Section 16 – Performance Testing – Bench.

The evaluation results confirm the performance characteristics of the SCENARIA are comparable to the predicate device and support our conclusion that the SCENARIA system is substantially equivalent.

Device Technological Characteristics

The SCENARIA's Gantry, X-ray Tube, X-ray Generator, and Patient Table specifications are substantially equivalent to the TOSHIBA Aquilion 64 Slice System. Likewise, the Helical Scanning, Image Processing, Display, Image Storage, and Performance features are equivalent to the predicate device. Lastly, the features related to dose which are available on the predicate device are also included on the SCENARIA. See Section 11 – Substantial Equivalence Discussion for additional information.

Therefore, the SCENARIA system is technologically equivalent in concept, function, and performance to the predicate device.

Safety and Effectiveness

The SCENARIA is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820.

Additionally this system is in conformance with the applicable parts of:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- IEC 60601-1-1:2000 Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard; Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004))
- IEC 60601-1-3: 1994 Edition 1.0, Medical electrical equipment - Part 1-3 - Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-ray Equipment.
- IEC 60601-2-32: 1994 Edition 1.0, Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment
- IEC 60601-2-44 (2002-11) Edition 2.1, Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography

Conclusions

The SCENARIA system has been developed and validated according to applicable standards. Testing has proven that the system is safe and effective for the indicated use. Risk and hazard analysis shows that there are no new safety issues associated with this system as compared with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Doug Thistlethwaite
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Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

APR - 8 2011

Re: K101888
Trade/Device Name: HITACHI SCENARIA Whole-body X-ray CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 25, 2011
Received: March 29, 2011

Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101888

Device Name: **HITACHI SCENARIA Whole-body X-ray CT System**

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101888